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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/943,550	08/30/2001	William Vanbrooks Harrison	AB-146U	9637

23845 7590 04/09/2004

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EXAMINER

OROPEZA, FRANCES P

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 04/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/943,550

Applicant(s)

HARRISON ET AL.

Examiner

Frances P. Oropeza

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 1/26/04 (Amendment A).
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6,9-12,19 and 21-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6,9-12,19 and 21-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. Claims 1, 2, 6, 9-12, 19, 21, 22 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ishikawa et al. (US 6464687) in view of Ben-Haim et al (US 6571127).

Ishikawa et al. disclose an implantable system that modulates blood flow/ circulatory perfusion (col. 13 @ 27-30) using a unit(s) that is near a vessel (col. 11 @ 5-10) to measure the a parameter such as blood flow, to deliver the drugs in response to the flow (col. 5 @ 34-39; col. 6 @ 25-32; col. 11 @ 5-7), and/or to provide electrical stimulation in response to the flow (col. 3 @ 53-56; col. 6 @ 25-32; col. 13 @ 24-27; col. 29 @ 33-36) by impacting the vessel/ smooth muscle/ skeletal muscle (tissue) /vascular tissue/ neural tissue (col. 2 @ 54-56 and 66-67; col. 4 @ 45-50; col. 9 @ 1-12; col. 11 @ 53-54). Control can be aggregated or the devices can operate independently, and the control can be internal or external (Abstract; col. 4 @ 35-39). The treatment site can be local or remote to the monitoring site (col. 7 @ 7-10). Flow in the vessel is monitored, and the drugs and electrical stimulation are controlled modulating the circulatory perfusion, creating hypoperfusion or hyperperfusion.

As discussed in the previous paragraph of this action, Ishikawa et al. disclose the claimed invention except for the method seeking to cause hypoperfusion/ hyperperfusion.

Ben-Haim et al. teach tissue treatment using electrical simulation and drugs for the purpose of changing perfusion to hypoperfusion and hyperperfusion states. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used electrical simulation and drugs to changing tissue perfusion between hypoperfusion and hyperperfusion

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states in the Ishikawa et al. system in order to reduce the strain on the cardiac tissue and optimizing the efficacy of the treatment for the patient (col. 5 @ 17-29; col. 15 @ 39-47).

2. Claims 3, 4, 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ishikawa et al. (US 6464687) in view of Ben-Haim et al (US 6571127) and further in view of Garfield et al. (US 6356777). As discussed in paragraph 1 of this action, modified Ishikawa et al. discloses the claimed invention except for stimulating the muscle at greater than 50 Hz to relax the muscle (claim 3), and stimulating the muscle at less than 50 Hertz to excite the muscle.

Garfield et al. teach muscle control using frequencies above and below 50 Hz to create a stimulated and relaxed muscle respectively for the purpose of altering the state of contraction. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used stimulation of the muscle above and below 50 Hz in the modified Ishikawa et al. system in order to provide a stimulation level known to create stimulation and relaxation of muscle tissue so levels of stimulation of the tissue/ muscles can be evaluated and optimal treatment levels adopted (Abstract; col. 3 @ 55-63; col. 11 @ 17-23).

3. Claims 5 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ishikawa et al. (US 6464687) in view of Ben-Haim et al (US 6571127) and further in view of Hobbs et al. (US 5916154). As discussed in paragraph 1 of this action, modified Ishikawa et al. disclose the claimed invention except for the stimulation level being less than about 1-10 mA.

Hobbs teaches tissue control using stimulation ranges of 1-5 mA for the purpose of relaxing the muscle, hence increasing flow in the vessel. It would have been obvious to one

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having ordinary skill in the art at the time of the invention to have used stimulation in the 1-5 mA range in the modified Ishikawa et al. system in order to provide a stimulation level known to create relaxation of the tissue so the flow level in vessel can be altered to an advantageous level for the patient to maintain an optimum pulse amplitude (Abstract; col. 2 @ 40-46).

4. Claims 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ishikawa et al. (US 6464687) in view of Ben-Haim et al (US 6571127) and further in view of Kieval et al. (US 6073048). As discussed in paragraph 1 of this action, modified Ishikawa et al. discloses the claimed invention except for electrical stimulation exciting the parasympathetic neural activity (claim 23), or inhibiting the sympathetic neural activity (claim 24).

Kieval et al. teaches neural stimulation using stimulation of the sympathetic/ parasympathetic systems for the purpose of inhibiting/ exciting neural activity. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used sympathetic and parasympathetic stimulation in the modified Ishikawa et al. system in order to provide control that enable the vascular tone to be adjusted so perfusion of the vascular system is optimized (col. 1 @ 39-49; col. 1 @ 60 – col. 2 @ 3).

Statutory Basis

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Fran Oropeza, telephone number is (703) 605-4355. The Examiner can normally be reached on Monday – Friday from 9 a.m. to 5 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Angela D. Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306 for regular communication and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Receptionist, telephone number is (703) 308-0858.

Frances P. Oropeza
Patent Examiner
Art Unit 3762

FP
4/2/04

Cingel. D. Sykes

ANGELA D. SYKES
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